UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA)))
v.) Criminal No. 05-10102-JLT
JOHN BRUENS, MARY STEWART, MARC SIROCKMAN, MELISSA VAUGHN)))
Defendants.)))

DEFENDANT MARC SIROCKMAN'S MEMORANDUM IN SUPPORT OF HIS MOTION FOR SEVERANCE FROM THE OTHER DEFENDANTS

The trial of defendant Marc Sirockman ("Sirockman") should be severed from the trial of defendants Mary Stewart ("Stewart"), John Bruens ("Bruens"), and Melissa Vaughn ("Vaughn") pursuant to Rule 14 of the Federal Rules of Criminal Procedure and the Sixth Amendment, because a joint trial would compromise Sirockman's trial rights and prevent the jury from making a reliable judgment about Sirockman's guilt or innocence. See United States v. Zafiro, 506 U.S. 534, 539 (1993); Fed. R. Crim. P. 14. In essence, the government is likely going to seek to introduce over half a dozen codefendant statements that are inadmissible hearsay against Sirockman, but admissible against each defendant-declarant. See generally, Crawford v. Washington, 541 U.S. 36 (2004); and Bruton v. United States, 391 U.S. 123 (1968). Because of the number of statements and defendants involved, the jury will not be able to render a reliable judgment on Sirockman's innocence if he is tried together with his codefendants and these numerous statements are submitted before the jury. Accordingly, this Court should sever Sirockman's trial from that of the other defendants.

BACKGROUND

On April 14, 2005, defendants Bruens, Stewart, Sirockman, and Vaughn were charged in an eight count indictment (the "Indictment") with conspiracy to violate the anti-kickback act and related substantive anti-kickback counts. During the course of the government's investigation, agents spoke with several of the defendants and other individuals who made statements that were recorded either before the grand jury or by the agents themselves in interview memorandums (FD-302s). The substance of these statements, and the anticipated testimony relating to these statements, provide the bases for Sirockman's severance. Specifically, the following inflammatory statements may be admissible against each respective defendant-declarant but are undeniably inadmissible against Sirockman. Thus, Marc Sirockman's right to a fair trial would be unduly compromised if they were admitted in a joint trial of which he was a part.

Defendant Mary Stewart's Statements

Stewart was interviewed by the FBI on March 6, 2002 by Agents Cathy Plesha and Kimberly Vagos. The agents took notes during the conversation and the next day typed up a memorandum of the discussion. <u>See</u> Exhibit A. Accordingly, Sirockman expects that the agents will testify that Mary Stewart told them the following information:¹

- (a) that the Cannes conference program was a "momentary lapse of judgment" by John Bruens;
- (b) that Vaughn got "upset" about the whole conference idea;
- (c) that Stewart requested that Sirockman be terminated because of his "business practices";
- (d) that there were "rumors" that Sirockman had "manipulated grant money without authorization; and

¹ It is possible that the agents will also testify as to other statements made by Stewart under the umbrella of Fed. R. Crim. P. 404(b) evidence. This anticipated testimony is similarly inadmissible against Sirockman and thus further supports his motion for severance.

(e) that Sirockman was "aggressive, too pushy" and "a cowboy, on his own doing his stuff."

Additionally, the government may seek to introduce an undated, unsigned document entitled "Feedback on Marc Sirockman" which it apparently believes was authored by Mary Stewart. See Exhibit B, S 0006875-76. Assuming that it can prove that Stewart created or authored the document, the government will likely attempt to introduce this as a defendant admission against Stewart.

As discussed more fully <u>infra</u>, all of these statements allegedly made by Stewart are inadmissible hearsay as to Sirockman and thus cannot be used against him.

Defendant John Bruens' Statements

Similarly, the prosecution will likely seek to introduce inculpatory statements attributed to defendant John Bruens. For example, relator Kimberly Jackson testified that at a regional director's meeting on March 1, 1999:

John Bruens told the [regional] directors to ask our top, top, top prescribers to put 30 patients on [Serostim] that month immediately, and if they did that, they would get a free trip to Cannes, France, for a nutritional AIDS conference that was coming up.

Jackson 05/02/02 GJ Tr. at 25. Jackson offered similar testimony regarding John Bruens' statements at the March 1, 1999 regional directors' meeting when she testified before the grand jury for a third time in December 2003. See Jackson 12/09/03 GJ Tr. at 58.

As discussed more fully <u>infra</u>, all of these statements allegedly made by Bruens are inadmissible hearsay as to Sirockman and thus cannot be used against him.

Defendant Melissa Vaughn's Statements

Finally, the government will also seek to introduce a voicemail message attributed to Melissa Vaughn in which she allegedly states:

Hey guys - This message is going to the RDs and I'm going to copy Mary Stewart and John Bruens on this. I just had a couple of very sobering phone calls from two of my CCs who presented the Cannes, France program and I can tell you that they presented it in one of the best ways we could possibly present it. They presented it to doctors with whom they have excellent relationships and rapport, who are also top doctors and who had the potential to bring in 30 scripts for the next week or so, and who also would have been perfect for speaking, and so we had everything laid out perfectly - it was the perfect scenario.

These individuals each called me literally within five minutes of each other and could not express to me the horrible experience they went through and the things that were said to them by their doctors about this program: that it was unethical, that this is the very thing that the FDA looks for, that our drug is too good, our reputation is too good, our clinical consultants work too hard and the reputation is too positive to be stooping to such levels - why is Serono doing this? It just wasn't good - it was not good. I can't express it enough. I just wanted to let you know that we will not be doing this program in the south. We will get business, we will do what we need to do, but we won't go to desperate means that will compromise who we are as a company and who we are as individuals because I'm very proud of who we are and our product and essentially everything we represent as a company and as a product. I thought I'd pass this on to you just to give you some feedback and let you make your own decisions, but it was important enough for me to send it to the group.

See Exhibit C, SCV001-0122.²

As discussed more fully infra, all of these statements allegedly made by Vaughn are inadmissible hearsay as to Sirockman and thus cannot be used against him.

ARGUMENT

Α. Codefendants' Statements Are Inadmissible Against Sirockman

The Sixth Amendment guarantees a defendant the right to confront and cross-examine

Sirockman does not believe this alleged voicemail transcription is admissible hearsay under any theory. However, Sirockman assumes that the government may seek to introduce the substance of the statement through relator Kim Jackson's testimony to the extent she recalls it. Accordingly, Sirockman addresses it here as a basis for his severance motion.

witnesses against him. In <u>Bruton</u>, the Supreme Court recognized that admitting a codefendant's incriminating statement in a joint trial with the other defendant violated the defendant's right to cross-examination under the Sixth Amendment. 391 U.S. 123 (1968); <u>see also, Richardson v. Marsh</u>, 481 U.S. 200, 207 (1987) ("a defendant is deprived of his Sixth Amendment right of confrontation when the facially incriminating confession of a nontestifying codefendant is introduced at their joint trial, even if the jury is instructed to consider the confession only against the codefendant"). Additionally, the Court went even further to hold that a limiting instruction to a jury may not cure the prejudice and that severance may be necessary to protect a defendant's right to a fair trial,

A defendant may be prejudiced by the admission in evidence against a codefendant of a statement or confession made by that codefendant. This prejudice cannot be dispelled by cross-examination if the codefendant does not take the stand. Limiting instructions to the jury may not in face erase the prejudice.

Bruton, 391 U.S. at 132. See also, United States v. Albert, 73 F.2d 386, 388 (1st Cir. 1985).

Mary Stewart's statements regarding Sirockman and the Cannes program are the exact type of untested statements that must be excluded from a trial for Sirockman pursuant to <u>Bruton</u>. To wit, in response to police questioning, she implicated both Bruens and Sirockman, and arguably admitted that the Cannes program existed. In fact, Mary Stewart's statements to a law enforcement officer were the types of testimonial statements ruled inadmissible and inherently unreliable in the Supreme Court's landmark ruling in <u>Crawford</u>. 541 U.S. 36, 52 (Court ruled that testimonial statements are inadmissible against a defendant unless the defendant has an opportunity to cross-examine the declarant; "Where testimonial statements are at issue, the only indicium of reliability sufficient to satisfy constitutional demands is the one the Constitution actually prescribes: confrontation"). As Stewart cannot be compelled to testify regarding these

statements, as is her right under the Fifth Amendment, Sirockman will have no opportunity to cross-examine her as is his right under the Sixth Amendment.

All of Bruens' and Vaughn's statements are similarly inadmissible against Sirockman because they again violate his Confrontation Clause rights. While the government may attempt to argue that their statements are nonetheless admissible hearsay as co-conspirator statements under Fed. R. Evid. 801(d)(2)(E), such a claim fails. To qualify under the co-conspirator exception, a statement must have been made during the course, and in furtherance, of the alleged conspiracy. Bourjaily v. United States, 483 U.S. 121, 175 (1987). Vaughn's statements do not meet this standard because they were not intended to further the object of the conspiracy. In fact, Vaughn was clearly aiming to frustrate the very purpose of the alleged conspiracy as she stated in no uncertain terms that her region was not going to offer the Cannes trip at all, "I just wanted to let you know that we will not be doing this program in the south." See Exhibit C, SCV001-0122. Second, Bruens' statements are not admissible as co-conspirator statements because there is no evidence that a conspiracy of which Sirockman was a member, existed at the times Bruens made his remark. Bourjaily, 483 U.S. at 171; see also United States v. Gee, 695 F.2d 1165, 1169 (9th Cir. 1983) ("statements of alleged co-conspirators made before the time it can be shown by independent evidence that [the defendant] had joined the conspiracy are not admissible to show his participation").

As neither Bruens' nor Vaughn's statements should be admissible as co-conspirator statements, and it is likely that neither Bruens nor Vaughn will take the stand to provide Sirockman the opportunity to cross-examine them regarding their statements, his Sixth Amendment right to confrontation will be violated if the government is permitted to admit them as evidence through other witnesses. Again, the court in Bruton recognized the potential

prejudicial impact of these admissions and undeniably held that they are not admissible:

"Not only are the incriminations devastating to the defendant, but their credibility is inevitably suspect....the unreliability of such evidence is intolerably compounded when the alleged accomplice, as here, does not testify and cannot be tested by cross-examination. It was against such threats to a fair trial that the Confrontation Clause was directed."

391 U.S. at 136.

B. Severance Is the Appropriate Remedy Under These Circumstances

Federal Rule of Criminal Procedure 14 provides relief to criminal defendants who, although properly joined under Rule 8, are otherwise prejudiced by being named in the same indictment with their codefendants. Rule 14 provides that:

if it appears that a defendant or the government is prejudiced by a joinder of offenses or of defendants in an indictment or information or by such joinder for trial together, the court may order an election or separate trials of counts, grant a severance of defendants or provide whatever other relief justice requires.

Fed. R. Crim. P. 14. Though there is a preference in the federal system for joint trials of defendants who are indicted together, a district court should nevertheless sever a defendant under Rule 14 "if there is a serious risk that a joint trial would compromise a specific trial right of one of the defendants, or prevent the jury from making a reliable judgment about guilt or innocence." Zafiro v. United States, 506 U.S. 534, 539 (1993). The risk of an unfair trial is particularly acute in the context of a multi-defendant conspiracy trial, like the one the Government proposes to conduct here. The discretion to sever gives the Court an effective and broad power to minimize that risk. As Justice Stevens recognized in Zafiro:

[t]here will . . . almost certainly be multidefendant cases in which a series of separate trials would not only be more reliable, but also more efficient and manageable than some of the mammoth conspiracy cases which the Government often elects to prosecute. And in all cases, the Court should be mindful of the serious risks of prejudice and overreaching that are characteristic of joint trials, particularly when a conspiracy count is included in the indictment.

506 U.S. at 545 (Stevens, J., concurring).

The exercise of such discretion is perfectly applicable here where Sirockman faces potential prejudice from not just one statement from one defendant, but by multiple statements made by multiple defendants. In this case, cautionary instructions will not suffice, as the "mental gymnastics" the jury will have to perform in order to determine which of the half a dozen statements made by which of the four defendants are admissible against which defendant, are almost Herculean.³ The reality is that the jury would simply be unable to follow any limiting instructions as to which statement is admissible against one, but not the other three, defendants. And instead of attempting this complicated analysis, the jury would realistically just consider all of the statements against all of the defendants. "There are some contexts in which the risk that the jury will not, or cannot, follow instructions is so great, and the consequences of failure so vital to the defendant, that the practical and human limitations of the jury system cannot be ignored." Bruton, 391 U.S. 123, 135-36.

Similarly, because of the number of statements and defendants, redaction is not a sufficient remedy to cure the prejudice. Even assuming the statements are redacted to delete any references to defendants (which they absolutely must be to be admitted pursuant to <u>Bruton</u> and its progeny), Sirockman is still unfairly prejudiced because the jury will nonetheless be unable to sort out which of the many statements are admissible against which defendant. This is simply not a straightforward case, such as <u>Bruton</u> or <u>Richardson</u>, where only one statement and two defendants were at issue. Here, redaction will not solve the jury's inevitable bewilderment as to what can be considered against which defendant, as redaction will not change the confusing

-

Notably, Sirockman's own admissions, as described in Defendant Mary Stewart's Motion For Severance, will also contribute to the jury's confusion, as they add more statements the jury must hear, understand, and then remember to consider only against Sirockman and not the other defendants.

nature of the case and the fact that there are many statements and many defendants which must be sorted out. Thus, all of the numerous codefendant admissions are particularly prejudicial to Sirockman's right to a fair trial unless they are excluded as a whole,⁴ or his trial is severed from that of the codefendants.

CONCLUSION

The lesson taught by Justice Stevens is simple: in a multi-defendant conspiracy case, the Court must be keenly aware of its broad power to sever the trials of certain codefendants when it is necessary to protect those defendants' rights to a fair trial. Here, Sirockman has identified substantial risks to his individual trial rights and raised serious doubts about the ability of the jury to render a reliable judgment on his innocence if he is tried together with his codefendants. Severance of Sirockman's trial from those of his codefendants is the appropriate and most effective remedy for these problems. The Court, therefore, can and should exercise its broad discretion to sever his trial from the trials of Stewart, Bruens, and Vaughn.

Respectfully submitted,

MARC SIROCKMAN,

By his attorneys,

/s/ McKenzie E Webster
Tracy A. Miner, BBO # 547137
McKenzie E. Webster BBO #651204
Mintz, Levin, Cohn, Ferris,
Glovsky & Popeo, P.C.
One Financial Center
Boston, Massachusetts 02110

Dated: September 19, 2006

⁴ In lieu of ordering separate trials, the Court could also simply exclude all defendant admissions from the trial. This would also effectively preclude the jury from having to try and compartmentalize each of the numerous statements as admissible against only certain defendants.

EXHIBIT A

FEDERAL BUREAU OF INVESTIGATION

£	birt	:h				
i	ding	at	51	Four	Winds	

03/07/2002

Date of transcription

MARY KATHLEEN STEWART, date o Social Security Number Drive, Pembroke, Massachusetts, telephone number apprised to the purpose and identities of the interviewing agents.

STEWART provided the following information:

A bachelor's degree in marketing was obtained by STEWART from NORTHEASTERN UNIVERSITY, located in Boston, Massachusetts. While attending NORTHEASTERN UNIVERSITY, STEWART participated in the Co-Op Education Program and was employed at BRISTOL-MEYERS. This experience influenced STEWART to pursue employment with a pharmaceutical firm. During 1997, STEWART attended a two week executive management program at BABSON COLLEGE, located in Wellesley, Massachusetts. Currently, STEWART owns her own consulting firm, FENG SHUI BOSTON, INC., P.O. Box-368, Pembroke, Massachusetts, telephone number 781-294-7348.

In November 1991, STEWART commenced employment with SERONO LABORATORIES (SERONO) in California and held the position of Senior District Sales Manager. In March, 1994, STEWART moved to the New England region to assist with marketing SERONO's drug Saizen. In 1995, STEWART was re-assigned to assist with SERONO's drug, Serostim. While located with SERONO in the New England region, STEWART held the positions of Regional Director of Sales and then later, Vice President of Sales. In June, 2000, STEWART accepted a severance package from SERONO after being passed over for the position of Executive Vice President, which was granted to JAY MOHR.

A "couple of years" after Serostim had received approval from the FDA (U.S. Food and Drug Administration), STEWART recalled hearing that the clinical data submitted to the FDA was "incorrect." Also, in 2000, after STEWART had departed SERONO, she again heard "rumors" that the clinical data submitted by SERONO to the FDA was not correct. STEWART stated, she would not have known if the data to FDA had been "manipulated." When asked to explain these rumors that she had heard, STEWART did not respond. STEWART added, these "rumors" may have been the end product of people being angry with SERONO.

Investigation on	03/06/02	at	Pembroke,	MA		
	BS-87603-302				Date dictated	03/07/02
	THY PLESHA/cp MBERLY VAGOS					
چېدى دې						• .

This document contains neither recommendations nor conclusions of the FBI. It is the property of the FBI and is loaned to your agency; it and its contents are not to be distributed outside your agency.

4-21-5

209A-BS-87603-302

MARY KATHLEEN STEWART Continuation of FD-302 of

, On 23/26/22 ___, Page ___?

After the review of a document entitled, "FDA, Talk Paper, FDA Approves Drug For AIDS-Wasting," dated August 23, 1996, STEWART indicated, that this document improved her memory about the drug, Serostim. STEWART recalled, initially the FDA rejected a full approval for Serostim, before granting the drug an accelerated approval. Because the FDA granted an accelerated approval, SEROY O would have to conduct additional clinical trials to further evaluate Serostim. STEWART stated, she was aware that there was a delay in these clinical trials, but she did not know the reason for the delay.

For this time period, STEWART identified TOM LANG and MARLENE BOOTH, as the individuals, who were responsible for SERONO's compliance with FDA regulations. STEWART noted, that TOM LANG is currently the President of SERONO. STEWART identified in sequential order the following as having held the position of Medical Director at SERONO: HAL LANDY, M.D.; BOB KAUFMAN, M.D.; and JOHN SULLIVAN BULEAUX (phonetic). NORMA MUURAHAINEN, M.D., Ph.D., was identified as the current Medical Director.

After the review of a memorandum from HISHAM SAMRA, President of SERONO to JEFF GETTY and BILL THORNE, representing ACT UP Golden Gate, dated June 25, 1996, and in particular the phrases: မြောင်းသည်။ ကြောင်းသည်။

> "A yearly range of \$30,000 to \$36,000 for Serostim therapy is considered reasonable by both parties."

"To a clinical trial program that addresses FDA concerns, including determination of the optimal maintenance dose."

STEWART stated, "ideally" patients would only need one course of Serostim and that makes the "cap" of \$36,000.00 "reasonable." However, as STEWART calculated out loud, one, 12 week course of treatment would cost a patient about \$21,000.00 and anyone' who needed another course of treatment would easily exceed the \$36,000.00 "cap." According to STEWART, some physicians continuously prescribed Serostim for their patients, because once their patients were taken off the drug they would begin to lose weight.

According to STEWART, the SEROCARE/NORD Program was an "umbrella" for patients, who could not afford Serostim. After the review of a document entitled, "What The Treatment Continuation Program Offers You, " STEWART stated, that patients were to receive

209A-BS-87603-302

Continuation of FD-302 of	MARY	KATHLEEN	STEWART	
to rocard the troughting				

2	03,05,02	Page
		, b

Serostim "free" after an amount of \$36,000.00 had been paid. STEWART added, that there more stringent requirements for patients to qualify for the SEROCARE/NORD Program in comparison to other health plans. STEWART stated, this was because there was not enough of Serostim for everyone in the program. According to STEWART, only so much Serostim was allotted to the SEROCARE/NORD Program at any given time and this caused a waiting list or back log of patients for the drug. Reportedly, physicians became frustrated when their patients had to wait for the drug. STEWART noted, it was a difficult decision to decide, who needed the drug, but it was based on medical necessity by SERONO's medical director. STEWART added, body builders and anti-aging clinics were very interested in Serostim, but SERONO never "targeted" the anti-aging clinics or nursing homes.

STEWART was asked to comment on the possibility, that additional clinical trials for Serostim were delayed by SERONO, because the trials would indicate that patients were being over prescribed with 6 milligrams of the drug, considering the previous trials were based on 4 milligrams of Serostim. STEWART replied, she did not know.

STEWART was asked to explain, what she did when sales representatives told her that 6 milligrams of Serostim was too strong of a dosage and patients were complaining about aching body joints. STEWART replied, she "would not be surprised," if some sales representatives did not tell physicians that the number of prescribed milligrams of Serostim should correlate to a patient's weight.

During December, 1996, the Serostim Preferred Partners Program was initiated in order to find pharmacies to dispense. Serostim. After the review of a document entitled, "Serostim Preferred Partners, Serono" which listed twelve different pharmacies, STEWART stated, that this appeared to be an "old list," probably from the time period of when Serostim was in the TIND (Treatment Investigational New Drug) status for FDA approval. At some point, STEWART estimated, that there were 20 to 30 pharmacies which participated in the Serostim Preferred Partners Program. STEWART could not recall if, STADTLANDERS was the original pharmacy to dispense Serostim. STEWART stated, that she assisted with devising the Sterostim Preferred Partners Program, because SERONO needed reimbursement for the drug and initial attempts internally by SERONO to develop a reimbursement program had failed. According to STEWART, SERONO eventually discontinued this program in favor of

209A-BS-87603-302

2	MARY KA	THLEEN	STEWART	On 03/05,02 Page	. :
2: ntinuation of FD-302 of				, on, rage	

distribution by wholesalers, because the smaller pharmacies could not afford to stock Serostim, due to its high cost.

Pharmacies had to fulfill certain criteria in order to become a Serostim Preferred Partner. STEWART recalled, that there was a document listing this criteria, such as, the pharmacies had to have an expertise in treating individuals which were identified as being HIV positive, have a reimbursement expertise and ability to ship the drug, as well as, have supplies available. Initially, the criteria to identify these pharmacies did not include the dollar amount of Serostim dispensed, because there was no payment history for the drug. STEWART identified, California and then New York, as the first two states to reimburse on Serostim.

The following five individuals were identified by STEWART as being involved with the Serostim Preferred Partner Program: ELLEN FRANKS, who was STEWART's boss; CINDY BELL, who had oversight of marketing; JOHN HAUSS (phonetic), who handled the contracts and RICHARD AZULAY, who was involved with reimbursement.

STEWART stated, that the pharmacies participating in the Serostim Preferred Partners Program received a price discount from SERONO on Serostim. Price discounts were granted because these pharmacies would track the milligram amounts of Serostim dispensed. The bonuses paid by SERONO to its sales representatives were based upon this data. STEWART stated, she did not know, if these price discounts were passed onto MEDICAID, MEDICARE, CHAMPUS or the VETERANS AFFAIRS health benefit programs.

ELLEN FRANKS, as Executive Manager, had oversight of the Serostim Program, to include marketing and reimbursement. STEWART stated, that she was not certain, if FRANKS resigned or was "fired" by SERONO. STEWART believes, that ED PARRA, who was charge of the "trade group," could possibly have knowledge about price discounting. PARRA is currently residing in California. Another individual, whom STEWART believes may have information regarding price discounting is RICHARD AZULAY, who is still employed at SERONO.

As for the reporting of false data by the pharmacies, STEWART stated, she was unaware of any such activities. STEWART recalled, that there was a "gap" one time when the reported amount of Serostim dispensed was larger than the amount of drug manufactured. According to STEWART, this incident was never explained to her, but she thought it might have been a

209A-BS-87603-302

MARY KATHLEEN STEWART

_{,Om} 00,/06/02

ŗ

Continuation of FD-302 of

"distribution problem." STEWART added, that the data reporting by the pharmacies was "never exact."

After the review of a document entitled, "Serostim Pharmacy Data Collection Administrative Fee Agreement," STEWART stated, she was familiar with TDI Pharmacy located in Pittsburgh, Pennsylvania, which sold large amounts of Serostim in several states. STEWART never met the owner of TDI Pharmacy, TONY GREJDA, but he was described by some of SERONO's marketing personnel to her as "obnoxious and pushy." STEWART recalled, that she received many complaints about GREJDA, however, when requested to elaborate she did not provide any detail.

STEWART was requested to review a document entitled, "Serostim Preferred Partner Program, Background Information," and in particular the following phrase:

"MEDICAID guidelines prohibit manufactures from providing incentives or inducements to distributors for products / that are used in a MEDICAID population. Serostim is approximately 75% MEDICAID. The SERONO Legal Team has advised the discontinuation of the Preferred Partner Program agreement immediately."

STEWART stated, that "incentives and inducements" referred to the price discount pharmacies were given by SERONO for reporting the number of milligrams of Serostim dispensed. According to STEWART, the MEDICAID population was "targeted" by SERONO, because largely, the majority of HIV patients are on MEDICAID.

After the review of a document entitled, "Serostim Preferred Partner Program, Preferred Provider Impact," STEWART stated, she did not know the meaning of the phrase, "Loss of chargeback money (3.75% on purchases)." STEWART believes, that RICHARD AZULAY or JEFF HART would be able to explain this phrase. STEWART indicated, that she did not know KEVIN CAST, because he arrived at SERONO after she had departed the company.

While STEWART was employed at SERONO, the following individuals were identified as having the responsibility of assuring compliance with MEDICAID guidelines: ED PARRA, ELLEN FRANKS and RICHARD AZULAY. After STEWART departed SERONO, ISABELLE STILLGER headed this area under the direction of JAY MOHR. According to STEWART, STILLGER resigned from SERONO to spend more time with her children. JAY MOHR, who resides in Scituate,

209A-BS-87603-302

Continuation of FD-302 of MARY KATHLEEN STEWART

5

Massachusetts, departed SERONO within the last six months for a position with another pharmaceutical firm in Cambridge, Massachusetts.

When JEFFREY HART, was Vice President of Strategic Business Intelligence, he had oversight of data and reported this information to SERONO's management. Currently HART is assigned to Customer Service and STEWART added, "surprisingly" he is still employed at SERONO. KATHLEEN OGAR was identified as working under the supervision of HART or MELANIE WILKINS.

Initially, STEWART stated, that she could not recall the name, ABDULLAH BAAJ. STEWART believes, that ABDULLAH BAAJ was not involved with the Serostim Preferred Partners Program, but was possibly in charge of the Clinical Science Liaison Program. STEWART had the impression that ABDULLAH BAAJ held a Ph.D. degree or had a background with some type of medical training. According to STEWART, because SERONO did not like the "management style" of ABDULLAH BAAJ, he was assigned 2 or 3 sales accounts to handle for SERONO within Boston, Massachusetts, to "keep him busy."

After a review of the document entitled, "Serostim Preferred Partner Program, Reimbursement Examples," STEWART stated, that AWP refers to Average Wholesale Price, WAC refers to Wholesale Acquisition Costs and COT refers to Cost of Treatment. STEWART believes, "AWP -5%" may refer to a discount, but she was not certain.

AWP was identified by STEWART as not being the "real price," but an inflated price and this is done by everyone within the industry. STEWART described AWP as a built in "cushion" to create a pricing gap, but she could not recall the pricing for Serostim. Additionally, STEWART stated, she did not know, if SERONO reported to the Government an overly inflated AWP or if the discount price granted to some pharmacies was factored into the AWP pricing.

STEWART was requested to review and explain the following portion of an E-mail message:

"Voicemail sent by MELISSA VAUGHN Wednesday, March 3, 1999 regarding JOHN BRUENS offer to pay for certain high writing MDs flight and hotel in Cannes, France in April to attend an HIV Nutrition/Wasting program in exchange for 30 patient RXs during our 6 day sales blitz."

209A-BS-87603-302

	MARY KATHLEEN STEWART	On 03/05/02 Page
intinuation of FD-302 of		

STEWART remembers this incident and called it a "momentary lapse of judgement" by JOHN BRUENS. STEWART stated, the real intention was not to trade business for a trip to France. According to STEWART, VAUGHN got "upset" over this whole idea. Even though STEWART did not travel on this trip, she was aware that ALEXIS CORAZON M.D., had traveled to France. STEWART added, that ALEXIS CORAZON, M.D., was the only physician to accept this offer from SERONO. Currently, VAUGHN is working for a company in Colorado, and BRUENS is employed by another company in California. SUE WOMBLE, was an Administrative Assistant to BRUENS, who had oversight of the Marketing Department. Currently, SUE WOMBLE is located on the south shore region of Massachusetts.

STEWART was requested to review a memorandum from SUE -WOMBLE, Metabolic & Immune Therapy to HOWARD GROSSMAN, M.D., dated March 31, 199(9), and in particular the following phrase:

"Included with this invitation is an offer of a \$4,000 % grant for the purchase of airline tickets to Cannes. If you decide you would like us to make your flight arrangements for you, in lieu of the grant, we will purchase on your behalf one business class round trip ticket."

STEWART stated, obviously, she was wrong and other physicians had traveled to France.

According to STEWART, SERONO gave physicians "more attention" if they wrote numerous prescriptions for Serostim. STEWART described "attention" as buying physicians dinners, or "attention from SERONO management,"—but not a monetary compensation.

STEWART stated, that SERONO received "hundreds" of requests from physicians for money, and it was not from the "high writing" physicians as one would suspect. When requested to identify specific physicians, who made such requests, STEWART did not respond. It seemed to STEWART that physicians always wanted "something for nothing." It was quite common, according to STEWART, for physicians to request "educational grants" which paid for their air travel to attend HIV conferences sponsored by SERONO. STEWART stated, she was not certain if these physicians actually ever attended the conferences.

209A-BS-87603-302

Continuation of FD-302 of MARY KATHLEEN STEWART

om 03/06/02

3

The SERNONAIDS Program collects data on HIV patients and AIDS wasting patients. STEWART advised, that physicians submit data regarding their patients to SERONO, and they are in turn paid \$250.00 or \$300.00 for each completed form. SERONO made payments to the physicians on possibly a quarterly or some other pre-determined basis. Physicians submitted the forms to CINDY BEGL and ABDULLAH BAAJ. The Clinical Science Liaison Program was responsible for recruiting physicians, and they did so by sometimes identifying physicians through published studies. According to STEWART, all physicians participating in the program had to sign a contract agreement with SERONO. STEWART was not certain, if the physicians also received a fee for BIA (Bioelectrical Impedance Analysis) testing. Some physicians, STEWART believes, were "lent" BIA machines in order to perform BIA testing. ROSS PETTIT, was identified by STEWART as the Director of Medical Services, with oversight of this program. STEWART identified CINDY BELL as a close friend, who would know more facts about the SERONAIDS Program. STEWART added, CINDY BELL told her, she anticipates in about 2 weeks, to be "fired" by SERONO.

STEWART identified NORMA MUURAHAINEN, M.D., Ph.D., as SERONO's current Medical Director and BOB KAUFFMAN, M.D., as the former Medical Director, and both of these individuals had oversight of the SERONAIDS Program.

The purpose of BIA testing is to determine muscle mass and to track muscle mass over a time period. According to STEWART, sometimes sales representatives of SERONO performed BIA testing on patients by themselves and sometimes with the assistance of medical personnel within the physicians' offices. Typically, a sales representative would give a print-out of a patient's BIA test results to the physician, who reviewed it and decided, if the patient needed to be prescribed Serostim. STEWART stated, physicians would enter the BIA test results into the patient's medical record and not the sales representative, even though they may have actually performed the testing. In some instances, STEWART advised, medical personnel within the physicians' offices would ask the sales representatives to perform the BIA testing, because they were too busy or just did not want to do the testing. STEWART felt some medical personnel "pushed off" onto the sales representatives.

STEWART believes, there was no reimbursement by insurance programs for BIA testing. Also, STEWART is not aware of sales

209A-BS-87603-302

Continuation of FD-302 of

MARY KATHLEEN STEWART

.On 03/06/02

.

representatives telling physicians to bill for BIA testing, even when the testing was not performed by the physicians.

STEWART stated, "it was under" her leadership that some sales representatives, had reviewed patient medical records within physicians' offices in order to identify potential Serostim patients. According to STEWART, sales representatives were instructed not to do this, because it was not part of SERONO's sales plan.

After a review of the document entitled, Serostim Preferred Partner Program, Preferred Provider Impact," and in particular the phrase:

"Providers will not be held accountable to SERONO's SOP for BIAs etc..."

STEWART believes, that this refers to the pharmacies that performed BIA testing.

JOHN BRUENS and SCOTT LUNDIE (phonetic) from the Marketing Department were identified by STEWART as having had "control" over the BIA machines. *STEWART recalled, that SCOTT LUNDIE, whom she described as "computer literate," once changed the computer programs of the BIA machines and the sales representatives "revolted." When STEWART was requested for specifics regarding this "modification," she did not respond.

STEWART did not know why or the identity of the individual, who selected CPT codes 93720, 93721 and 93722 for BIA testing. After a review of the CPT descriptions for the previous mentioned codes, STEWART stated, that these codes do_not seem appropriate for BIA testing, because of the reference to respiratory. STEWART believes, RICHARD AZULAY, who has oversight of insurance reimbursement may be able to answer this question.

A document entitled, "BIA Fluid - Nutrition Assessment" was identified by STEWART as the form to record patient data measurements from BIA testing. In BIA testing, electrodes are placed on the patient's body which generates data. The sales representative would then load this data into the physician's computer. STEWART stated, "adjusting" or "fudging" data was not condoned by SERONO. According to STEWART, if any data was changed, such as the phase angle, the data would not be accurate.

209A-BS-87503-302

Continuation of FD-302 of

MARY KATHLEEN STEWART

_{.On} 03/06/02

10

After the review of a document entitled, Metabolic & Immune Therapy, MARY STEWART, Vice President, Sales," STEWART stated, that a "couple" of sales representatives "stood out in her mind." However, STEWART would not identify these individuals.

STEWART was requested to review a document entitled, "Feedback on MARC SIROCKMAN." Upon review STEWART stated, she was the one who had requested that MARC SIROCKMAN's employment with SERONO be terminated because of his "business practices." MARC SIROCKMAN worked in New Jersey and was a close, personal friend to ALEXIS CORAZON, M.D. According to STEWART, there were "rumors" that MARC SIROCKMAN had "manipulated" grant money without authorization. When MARC SIROCKMAN was approached by SERONO, he denied all allegations. STEWART described MARC SIROCKMAN as being "aggressive, too pushy" and "a cowboy, on his own; doing his stuff." Recently, STEWART advised, she had been contacted by MARC SIROCKMAN, who requested she provide an employment reference for him. STEWART added, no one has contacted her to date.

STEWART offered the following information regarding various SERONO sales representatives:

RAY HUDGENS was located in Florida, and STEWART had not heard his reported claim, if the phase angle of BIA test results were changed to the number 7, rather than the number 6, more patients would need Serostim. STEWART remembers RAY HUDGENS as a "consistent performer," who worked for either MELISSA VAUGHN or DAVE SAWIN, who were respectively Executive Area Directors.

ANGELO SAVERINO was located in Bronx, New York, and STEWART recalled nothing megative about SAVERINO, she described him as "quiet, low profile, not great sales and not a consistent performer." ANGELO SAVERINO was under the direction of ADAM STUPAK, who often had sales incentives for his sales representatives.

TODD SULLIVAN was located in New Jersey, and STEWART described him as being "very aggressive, someone she never trusted and sleazy." STEWART stated, she had no specific reasons for not trusting TODD SULLIVAN.

TODD MIKOLAJCZYK was also located in New Jersey and STEWART described him as an "OK guy."

209A-BS-87603-302

MARY KATHLEEN STEWART

ൂ 03/06/02

1.

Continuation of FD-302 of

PHIL BLACK was located in California, and STEWART was "shocked" when she heard he had been terminated by SERONO for doing something wrong regarding a hospital. STEWART stated, she could not recall the details regarding PHIL BLACK.

According to STEWART, there is so much jealousy among sales representatives that this often made it difficult to discriminate between truth and jealousy. STEWART offered the opinion that MELISSA VAUGHN, DAVE SAWIN and VANCE LNU (Last Name Unknown) were "sacrificial lambs," who were terminated by SERONO.

STEWART stated, she had "only heard" about ABDULLAH BAAJ's "open label study" of prescribing Serostim in the treatment of lipodystrophy, and that the study had to be discontinued. After the review of a document entitled, "An Open Label Study to Determine the Effect of Low Dose Growth Hormone on Visceral Fat Accumulation in HIV-Infected Patients," STEWART stated, that this document had to be an early draft of the final paper. After the review of a document entitled, "SERONO, Notice of Compliance," STEWART stated, that this was for the recall of promotional literature. Since ABDULLAH BAAJ had only been given 2 or 3 accounts in Boston, Massachusetts, STEWART identified, CHRISTINE DRISCOLL and TODD WILLINDER, both sales representatives, as individuals who would have knowledge regarding ABDULLAH BAAJ's lipodystrophy study. STEWART believes, ABDULLAH BAAJ's "open label study" was limited to these 2 or 3 accounts in Boston. STEWART was not certain, if any information from this study was ever entered into the SERONAIDS Program nor the reason that ABDULLAH BAAJ departed SERONO. CHRISTINE DRISCOLL was identified as still employed at SERONO, but someone who has been talking for sometime while of leaving SERONO.

As for the drug, Serostim, STEWART stated, she "believes" that the drug has "saved" many peoples' lives. Also, STEWART told of participating in telephone hot-line calls regarding AIDS and that she heard much "positive feed-back," from patients regarding Serostim.

Before STEWART departed SERONO, she was put on an "International Team" for Serostim and traveled almost on a weekly basis between Massachusetts and Switzerland. According to STEWART, she believes this assignment was given to her in consolation for being passed over for the position of Executive Vice President, which was granted to JAY MOHR. Eventually, STEWART stated, all the

Case 1:05-cr-10102-JLT Document 63-2 Filed 09/19/2006 Page 13 of 13

FD-302a (Rev. 10-6-95)

209A-BS-87603-302

Continuation of FD-302 of

MARY KATHLEEN STEWART

03/06/02

1.2

traveling made it too difficult for her, and she decided to resign her position with SERONO.

EXHIBIT B

Feedback on Marc Sirockman

Business Practices

- Numerous Allegations of encouraging/asking Clinical Consultants to offer inappropriate incentives to obtain Serostim prescriptions.
- Establishing an uncomfortable work environment that the CC needs to do "whatever it takes" to get the business.
- CC's feeling ethics are comprimised and resigned as a result: CE/JR
- This reputation of "buying the business" is known in the Region and commented on by physicians
- 8/11/99: Hanneman Hospital Clinic: Field visit with D. King. Serostim flyer seen. Marc asked DK several times to "call them up and offer them \$50/Rx for every Rx we get....offer the \$ and get back to me". Flyer was from Landis Osbourne, Research Coordinator of Serostim ID study set up by CSL, Caryl Moscardini.
- 3 CCs referred to direction of utilizing grants and speakers funds as a way to incentivize physicians who write for Serostim. Suggested that physiciaan does not really have to speak or can cancel last minute and still pay them. Allegations of filling out fictitious forsm
- Encouraged CCs to "Be creative...Think out of the Box....Ask the Doctors what they want and give it to them...You have to get something to give something"
- Encouraged CCs to find strip mall clinics that have high Medicaid populations, money motivated, unethical, unscrupulous physicians,
- During Sales meetings, after HOPS left, "We will do it our way, let's keep this quiet"
- Promoting SeronAIDS inappropriately: as a sales tool and "money maker" for the
- Utilizing RDs to screen patients on a regular basis without approval or discussion with VP of Sales. Encouraged CCs to pay the RDs more than BTG is paying.
- Mgmt by fear/intimidation: Sell like him in aggressively...My way or the highway mentality....Told to do whatever you can to make a sale.
- Marc asked CE to promise a physician you'll buy him a digital camera if you put 20 patients on Serostim. (Community Health Network, Rochester, NY). CE asked never to bring you back again due to your aggressive, offensive style. Also offered to buy them a fax if they used Stadtlanders instead of their preferred pharmacy so region would get the sales credit.

Hostile Work Environment

- Alleged favoritism: appeared to favor his own personal hires vs. those inherited from KJ or AS: CE resigned; JR resigned; JA resigned; DK wants to resign and will if he stays.
- Hired all 6 white males like himself who are "aggressive". Feeling of "Good Old Boy" Network.
- Allegations of treating female different than male and taking away accounts from female to give to male CC.
- Allegedly said to DK, "It's better to have a man cover this account" when Watkins and Philadelphia Fight. (Dr. Onderson)
- Changing meeting location of 6/15/99 and not telling Donna. She had to call Marc to
 find out where they were. Donna at Doubletree. Three men at the Marriot Courtyard.
 Donna had to keep calling Marc to find out where they were. Marc never informed
 her of the change. She was the most prepared from a reimbursement standpoint.j
- Veiled threats of hurting future promotional opportunities when DK said she wanted
 to call me. Ie., "Go ahead...that will be amusing to see... Is that the way a future RD
 would handle it going over my head?....I'm the manager here... I make the decisions
 when questioned on why accounts were moved.
- As a result of moving accounts little by little, M. Jennings and D. King are no longer on speaking terms due to way situation was handles.
- 7/13/99; MJ set up speaker program with DK's account, Dr. Onderson. DK not informed. Marc comes in with Mike. On 8/22 gives Mike the account.
- CE was forced out. He left Serono without having another job due to harrassment from Marc. He felt his nursing license would be compromised by being asked to do unethical things to get the business.
 - "If you have to walk around the hospital with \$100 bills coming out of your pockets, do it to get the business"
- Sarcastic comments after viewing the Dr. Liporace patient video... "I shed a tear for him...followed by inappropriate comments about his house/car/\$ motivation"
- Disparaging remarks about former RD,"I'm not Kim....Old team was old dinasours"
- Either Marc likes your or phases you out. (CE). Didn't feel comfortable with Marc.
 Couldn't take him to my accounts. Very stressful. Had to get rid of him. Marc kept
 hammering him over and over about the numbers. Marc wanted him to work 7 am to
 7pm.

EXHIBIT C

Voicemail sent by Melissa Vaughn Wednesday, March 3, 1999 regarding John Bruens offer to pay for certain high writing MDs flight and hotel in Cannes, France in April to attend an HIV Nutrition/Wasting program in exchange for 30 patient Rxs during out 6 day saics office.

"Hey guys - This message is going to the RDs and I'm going to copy Mary Stewart and John Bruens on this. I just had a couple of very sobering phone calls from two of my CCs who presented the Cannes, France program and I can tell you that they presented it in one of the best ways we could possibly present it. They presented it to doctors with whom they have excellent relationships and rapport, who are also top doctors and who had the potential to bring in 30 scrips for the next week or so, and who also would have been perfect for speaking, and so we had everything laid out perfectly - it was the perfect scenario.

"These individuals each called me literally within five minutes of each other and could not express to me the horrible experience they went through and the things that were said to them by their doctors about this program: that it was unethical, that this is the very thing that the FDA looks for, that our drug is too good, our reputation is too good, our clinical consultants work too hard and the reputation is too positive to be stooping to such levels – why is Serono doing this? It just wasn't good – it was not good. I can't express it enough. I just wanted to let you know that we will not be doing this program in the south. We will get business, we will do what we need to do, but we won't go to desperate means that will compromise who we are as a company and who we are as individuals because I'm very proud of who we are and our product and essentially everything we represent as a company and as a product. I thought I'd pass this on to you just to give you some feedback and let you make your own decisions, but it was important enough for me to send it to the group."

Ray Hudgens and Adam Whitehurst were the CCs who asked the physicians. One MD was Dr. Piperato.